UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

23838 7590 01/31/2006

KENYON & KENYON LLP
1500 K STREET N.W.
SUITE 700
WASHINGTON, DC 20005

EXAMINER	
TSOY, ELENA	
ART UNIT	**PAPER NUMBER**
1762	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,216	RICHARD, ROBERT E.	
	Examiner	Art Unit	
	Elena Tsoy	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6,9,10,12-15,28,29,31 and 33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6,9,10,12-15,28,29,31 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

Amendment filed on 12/22/2005 has been entered. Claims 3-6, 9-10, 12-15, 28-29, 31, and 33-36 are pending in the application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 12, 14-15, 31, 33-36, 4-6, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al (US 6,627,246) in view of Rowan et al (US 6872225), further in view of Sand (US 4,598,006).

Mehta et al are applied here for the reasons of record set forth in paragraph 2 of the Office Action mailed on 9/30/2005. Mehta et al further teach that stents generally are coated by simple dip or spray coating of the stent with a polymer and a pharmaceutical/therapeutic agent or drug for delivery (See column 1, lines 25-33). However, it is preferred to use a polymer and a pharmaceutical/therapeutic agent or drug in a SCF exhibiting high solvent power for many normally insoluble substances instead of conventional solvents (See column 2, lines 5-33). In other words, Mehta et al teach that the drug can be incorporated into the polymer coating on the medical device by coating the stent with a solution/suspension of the drug and the polymer in SCF. Mehta et al fail to teach that the drug can be incorporated into the polymer coating on the stent by swelling the coating in a supercritical fluid devoid of coating prior to exposing the

coating on the coated medical device to the supercritical fluid that has been interfaced with the therapeutic.

Rowan et al teach that a drug for delivery can be incorporated into a polymer coating on a stent (See column 1, lines 6-7) by swelling the coating in a solution of pharmaceutical active in a solvent which swells the coating, then evaporating the solvent to remove 10 to 100% of total solvent, to produce a pharmaceutical active loaded stent (See column 3, lines 10-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated a drug into a second polymer coating in Mehta et al using a method of Rowan et al instead of using a solution of the second polymer and a drug by immersing a stent coated with a first polymer layer and a second polymer layer into a solution of a drug in a solvent which swells the coating thereby incorporating the drug into a swollen coating, followed by evaporating the solvent, with the expectation of providing the desired drug loaded stent for delivery of the drug, as taught by Rowan et al.

Since Mehta et al teach that SFC can successfully substitute a conventional solvent in a coating process, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used SFC instead of the conventional solvent with the expectation of providing the desired the desired drug loaded stent for delivery of the drug.

One of ordinary skill in the art would have reasonable expectation of success in using SFC in Mehta et al in view of Rowan et al since Sand shows that a polymer such as polyolefins or EVA (See column 3, lines 55-59) can be impregnated with an impregnation material such as a pharmaceutical composition by contacting the polymer article with a solution of the pharmaceutical composition in a volatile swelling agent such as carbon dioxide (See column 3, line 24) maintained at supercritical conditions for the volatile swelling agent in autoclave (See

column 4, lines 3-39), causing to swell the polymer and incorporate the pharmaceutical composition (See column 3, lines 60-68), and then reducing the pressure so that the volatile swelling agent diffuses out of the thus impregnated polymer (See Abstract).

3. Claims 3, 9, 13, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al in view of Rowan et al, further in view of Sand, and further in view of Allen et al (US 6,495,204).

Mehta et al in view of Rowan et al in view of Sand are applied here for the same reasons as above. Mehta et al in view of Rowan et al in view of Sand fail to teach that: (i) the medical device can be coated by spray-on deposition (Claim 3) using nozzle (Claim 28); (ii) collecting residual SCF and therapeutic (Claim 9).

As to (i), Allen et al teach that typically coating with the use of SCFs involves the application of one or more modifying agent by batch soaking in an enclosed chamber or includes processes based upon spraying from a pressurized chamber through a narrow nozzle (See column 1, lines 65-67). Upon spraying of the fluid onto the substrate, the supercritical fluid carrying the coating material leaves the high pressure environment and is exposed to a normal atmospheric environment (See column 2, lines 7-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used spray-on deposition in Mehta et al in view of Rowan et al in view of Sand instead of a batch soaking in an enclosed chamber since Allen et al teach that coating with the use of SCFs can be typically done either by a batch soaking in an enclosed chamber or by spray-on deposition.

As to (ii), Allen et al further teach that SCF and a coating material can be removed and recycled for further use (See column 6, lines 60-62).

As to claim 6, Mehta et al teach that the therapeutic agent can be may be mixed with SCF to form a true solution or may be in a suspension of particles (See column 9, lines 35-50). It is well known that colloidal suspensions may be referred to as "colloidal solutions" because the extremely small particle size. Obviously swelled polymer would be able to incorporate the therapeutic agent from colloidal solutions because of the extremely small size of the agent.

As to claim 29, Allen et al further teach that an injector 30 (with a nozzle) can be configured to inject the process fluids tangentially, perpendicularly, or at any other functional angle (claimed manipulating the nozzle to change the direction of the SCF flow). For example, a tangentially angled injector could be used in a chamber having two larger opposing regions, separated by a constricted medial region. Additionally, multiple injectors can be used to ensure that all surfaces of the non-equidimensional substrate can be appropriately modified. Alternatively, a perpendicular injector at close proximity to a substrate could be used to impregnate the substrate with higher pressure injections. In another embodiment, the processing chamber can utilize a treatment mixture comprised of the modifying agent and a carrier for applying the modifying agent, wherein the carrier is selected from the group consisting of supercritical fluid. See column 5, lines 48-63.

4. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al in view of Rowan et al, further in view of Sand, further in view of Allen et al, and further in view of Kuo et al (US 5098194).

Mehta et al in view of Rowan et al in view of Sand in view of Allen et al are applied here for the same reasons as above. Mehta et al in view of Rowan et al in view of Sand in view of Allen et al fail to teach that spraying can be performed with manipulating a nozzle to change the direction in which SCF is directed towards the stent.

Kuo et al teaches that a stationary or a moving spray gun can be used for applying coating compositions containing SCF to coil steel, or parts, etc. (See column 2, lines 60-61; column 5, lines 24-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a moving spray gun for spraying coating with the use of SCFs in Mehta et al in view of Rowan et al in view of Sand in view of Allen et al since Kuo et al teaches that a moving spray gun can be used for applying coating compositions containing SCF to coil steel, or parts, etc.

Response to Arguments

5. Applicant's arguments with respect to claims 3-6, 9-10, 12-15, 28-29, 31, and 33-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

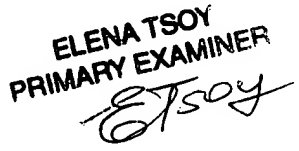
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is 571-272-1429. The examiner can normally be reached on Monday-Thursday, 9:00AM - 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elena Tsoy
Primary Examiner
Art Unit 1762



January 24, 2006